

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY) MDL NO. 1456
AVERAGE WHOLESALE PRICE)
LITIGATION) CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO) Judge Patti B. Saris
ALL CONSOLIDATED PRIVATE CLASS)
ACTIONS)

**FUJISAWA HEALTHCARE INC. AND FUJISAWA USA, INC.'S
ANSWER TO PLAINTIFFS' FOURTH AMENDED MASTER
CONSOLIDATED CLASS ACTION COMPLAINT**

Defendants Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. (collectively referred to as “Fujisawa”), for their Answer to Plaintiffs’ Fourth Amended Master Consolidated Class Action Complaint Amended To Comply With Court’s Class Certification Order (“FAMCC”) (filed by counsel for proposed class plaintiffs on March 1, 2006), state as follows:

Preface

The FAMCC improperly and repetitively refers to Fujisawa and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Fujisawa or other defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to appraise Fujisawa in any meaningful sense of the allegations asserted against it. Fujisawa has nevertheless attempted to respond to Plaintiffs’ allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct or actions of other defendants or entities, Fujisawa is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis,

Fujisawa denies those allegations. Fujisawa states that it is answering Plaintiffs' allegations on behalf of itself only, even when Plaintiffs' allegations refer to alleged conduct by Fujisawa and other persons or entities.

The FAMCC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the FAMCC are vague or conclusory. The FAMCC also includes terms which are undefined and which are susceptible of different meanings.

The FAMCC also contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine or the joint-defense privilege, Fujisawa reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiffs may have in their possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Fujisawa denies each and every allegation contained in the FAMCC, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculations which are contained in any averment or in the FAMCC as a whole. Moreover, Fujisawa specifically denies any allegations contained in headings, footnotes, the Table of Contents, unnumbered paragraphs, exhibits, attachments, and appendices in or referenced by the FAMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

I. INTRODUCTION

1. Fujisawa admits that Plaintiffs seek to bring this action as alleged in Paragraph 1 of the FAMCC. Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged.

2. Fujisawa denies the existence of, or its participation in, any “conspiracy” as alleged in Paragraph 2 of the FAMCC. To the extent the allegations in Paragraph 2 of the FAMCC allege a conspiracy between Fujisawa and various publishing entities, no response is required because these allegations, which formed the basis of Count I of the Plaintiffs’ Amended Master Consolidated Class Action Complaint, were dismissed with prejudice by the Court’s Order dated February 25, 2004. To the extent the allegations in Paragraph 2 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

3. To the extent the allegations in Paragraph 3 of the FAMCC are directed to persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. Fujisawa admits that it manufactures certain medicines that are covered under Medicare Part B, and that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Fujisawa admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. Fujisawa admits that AWPs for its medicines published in trade publications may be higher than the prices ultimately paid by

providers purchasing such medicines from wholesalers and distributors. Fujisawa denies the remaining allegations in Paragraph 3 of the FAMCC that pertain to it.

4. To the extent the allegations in Paragraph 4 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP, and further admits that Medicare Part B medicines are generally, but not always, administered in a healthcare provider's office. Fujisawa denies the remaining allegations in Paragraph 4 of the FAMCC that pertain to it.

5. Fujisawa admits that AWP is used by certain entities for reimbursement purposes. Fujisawa denies the existence of, and its participation in, any "AWP scheme" as alleged in Paragraph 5 of the FAMCC. To the extent the allegations in Paragraph 5 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 5 of the FAMCC that pertain to it.

6. To the extent the allegations in Paragraph 6 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the FAMCC, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged. Fujisawa denies the remaining allegations in Paragraph 6 of the FAMCC that pertain to it.

7. Fujisawa denies the existence of, and its participation in, any “high profit scheme” as alleged in Paragraph 7 of the FAMCC. To the extent the allegations in Paragraph 7 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 7 of the FAMCC that pertain to it.

8. Fujisawa admits that Plaintiffs have filed attachments to the FAMCC. To the extent the allegations in Paragraph 8 or any referenced attachments to the FAMCC are deemed to include allegations against Fujisawa, they are denied. Fujisawa denies the remainder of the allegations in Paragraph 8 of the FAMCC that pertain to it.

II. JURISDICTION AND VENUE

9. Fujisawa admits that this Court has federal question subject matter jurisdiction. Fujisawa avers that it is not a defendant in the Texas action referenced in Paragraph 9 of the FAMCC, but Fujisawa admits that, upon information and belief, diversity jurisdiction exists.

10. Fujisawa admits the allegations in Paragraph 10 of the FAMCC.

11. Fujisawa admits the second sentence of Paragraph 11 of the FAMCC and admits that it does business in this district. Fujisawa denies the remaining allegations in Paragraph 11 of the FAMCC.

12. Fujisawa admits the allegations in Paragraph 12 of the FAMCC.

III. PARTIES

A. Plaintiffs

13. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the FAMCC and, therefore, denies those allegations.

1. Proposed Class 1 Representatives (Medicare Part B Beneficiaries)

14-24. Fujisawa admits that Plaintiffs have proposed the individuals listed in Paragraphs 14-24 of the FAMCC as purported class representatives, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged and denies that the individuals are proper class representatives. To the extent that paragraphs 14-24 of the FAMCC assume or allege improper conduct by Fujisawa, Fujisawa denies such allegations. As to all remaining allegations in Paragraphs 14-24, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 14-24 of the FAMCC and, therefore, denies those allegations. Further, Fujisawa provides no response throughout this answer with respect to allegations regarding the following drugs because they were struck by Judge Saris' April 13, 2006 order and therefore are not at issue: adenosine, bupivacaine, ciprofloxacin hydrochloride, dexamethasone, diltiazem hydrochloride, dopamine hydrochloride, enalaprilat, epinephrine, famotidine, glycopyrrolate, hydromorphone, ketrolac tromethamine, levofloxacin, lidocaine hydrochloride, magnesium sulphate, midazolam, midazolam hydrochloride, morphine sulfate, neostigmine methylsulfate, potassium chloride, promethazine, ringers lactated with dextrose injectable, propofol, succinylcholine chloride, vancomycin sulphate, and vercuronium bromide.

2. Proposed Class 2 Representatives (MediGap Payors)

25-31. Fujisawa admits that Plaintiffs have proposed the individuals listed in Paragraphs 25-31 of the FAMCC as purported class representatives, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged and denies that the individuals are proper class representatives. Fujisawa admits that Plaintiffs have filed attachments to the FAMCC. To the extent the allegations in any referenced attachments to the FAMCC, or in documents not attached but otherwise referenced in the FAMCC are deemed to include allegations against Fujisawa, they are denied. To the extent that paragraphs 25-31 of the FAMCC assume or allege

improper conduct by Fujisawa, Fujisawa denies such allegations. As to all remaining allegations in Paragraphs 25-31, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 25-31 of the FAMCC and, therefore, denies those allegations. Further, Fujisawa provides no response throughout this answer with respect to allegations regarding the following drugs because they were struck by Judge Saris' April 13, 2006 order and therefore are not at issue: adenosine, bupivacaine, ciprofloxacin hydrochloride, dexamethasone, diltiazem hydrochloride, dopamine hydrochloride, enalaprilat, epinephrine, famotidine, glycopyrrolate, hydromorphone, ketrolac tromethamine, levofloxacin, lidocaine hydrochloride, magnesium sulphate, midazolam, midazolam hydrochloride, morphine sulfate, neostigmine methylsulfate, potassium chloride, promethazine, ringers lactated with dextrose injectable, propofol, succinylcholine chloride, vancomycin sulphate, and vercuronium bromide.

3. Proposed Class 3 Representatives (TPPs and Consumers for AWP-Based Charges on Physician Administered Drugs Outside of Medicare)

32-61. Fujisawa admits that Plaintiffs have proposed the individuals listed in Paragraphs 32-62 of the FAMCC as purported class representatives, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged and denies that the individuals are proper class representatives. Fujisawa further denies that Plaintiffs have properly proposed the individuals in Paragraphs 32-62 as class representatives, because Plaintiffs have failed to specifically allege particular representatives for particular defendants. Fujisawa admits that Plaintiffs have filed attachments to the FAMCC. To the extent the allegations in any referenced attachments to the FAMCC, or in documents not attached but otherwise referenced in the FAMCC are deemed to include allegations against Fujisawa, they are denied. To the extent that paragraphs 32-61 of the FAMCC assume or allege improper conduct by Fujisawa, Fujisawa denies such allegations. As to all remaining allegations in Paragraphs 32-61, Fujisawa is without

knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 32-61 of the FAMCC and, therefore, denies those allegations. Further, Fujisawa provides no response throughout this answer with respect to allegations regarding the following drugs because they were struck by Judge Saris' April 13, 2006 order and therefore are not at issue: adenosine, bupivacaine, ciprofloxacin hydrochloride, dexamethasone, diltiazem hydrochloride, dopamine hydrochloride, enalaprilat, epinephrine, famotidine, glycopyrrolate, hydromorphone, ketrolac tromethamine, levofloxacin, lidocaine hydrochloride, magnesium sulphate, midazolam, midazolam hydrochloride, morphine sulfate, neostigmine methylsulfate, potassium chloride, promethazine, ringers lactated with dextrose injectable, propofol, succinylcholine chloride, vancomycin sulphate, and vercuronium bromide.

62. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 of the FAMCC, and, therefore, denies those allegations.

4. Public Interest Group Plaintiffs

63-67. Fujisawa admits that Plaintiffs VPIRG, WCA, StateWide, CANY, and CCJ purport to bring this action as alleged in Paragraphs 63-67 of the FAMCC, but Fujisawa denies that these Plaintiffs have standing to bring the alleged action. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraphs 63-67 of the FAMCC and, therefore, denies those allegations. To the extent that Plaintiffs are raising claims under the Clayton Act, those counts have been voluntarily dismissed and, therefore, do not require a response.

B. Defendants

68-69. Fujisawa denies the allegations in Paragraphs 68-69 to the extent they pertain to Fujisawa. Fujisawa denies the existence of, or participation in, any "conspiracy" as alleged in

Paragraph 69 of the FAMCC. To the extent the allegations in Paragraphs 68-69 of the FAMCC refer to the knowledge, conduct, or actions of persons, entities, or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

70-71. The allegations in Paragraphs 70-71 of the FAMCC are directed to other defendants and require no response from Fujisawa. To the extent the allegations in Paragraphs 70-71 of the FAMCC are deemed to include allegations against Fujisawa, those allegations are denied.

72. The claims in Paragraph 72 related to Together Rx have been voluntarily dismissed, and, therefore, do not require a response. To the extent a response is required, Fujisawa denies the allegations in Paragraph 72.

73-107. The allegations in Paragraphs 73-107 of the FAMCC are directed to other defendants and require no response from Fujisawa. To the extent the allegations in Paragraphs 73-107 of the FAMCC are deemed to include allegations against Fujisawa, those allegations are denied.

9. The Fujisawa Group (Fujisawa HealthCare, Fujisawa USA)

108. Fujisawa admits that Fujisawa Healthcare was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa admits that Fujisawa Healthcare was an indirect subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation. Fujisawa denies the remaining allegations in Paragraph 108 of the FAMCC.

109. Fujisawa admits that Fujisawa USA was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa admits that

Fujisawa USA was an indirect subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation. Fujisawa denies the remaining allegations in Paragraph 109 of the FAMCC.

110. Fujisawa admits that, among other things, Fujisawa USA previously manufactured certain prescription medications that are covered by Medicare Part B. Fujisawa denies the remaining allegations in Paragraph 110 of the FAMCC.

111-144. The allegations in Paragraphs 111-144 of the FAMCC are directed to other defendants and require no response from Fujisawa. The claims related to Together Rx have been voluntarily dismissed and, therefore, do not require a response. To the extent a response is required, the Together Rx allegations are denied. To the extent the allegations in Paragraphs 111-144 of the FAMCC are deemed to include allegations against Fujisawa, those allegations are denied.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

145. Paragraph 145 simply characterizes the FAMCC, accordingly no response is required. To the extent a response is deemed required, and to the extent the allegations in Paragraph 145 of the FAMCC are directed to other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations in Paragraph 145 of the FAMCC that pertain to it.

146. Fujisawa is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 146 of the FAMCC, except to admit that prescription drugs are dispensed to patients by different types of medical providers, including physicians and retail pharmacies.

147-154. To the extent the allegations in Paragraphs 147-154 of the FAMCC refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Further answering Paragraph 147 of the FAMCC, Fujisawa admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Further answering Paragraphs 148 and 149 of the FAMCC, Fujisawa admits that pharmaceutical industry pricing publications periodically report AWPs for prescription medicines sold in the United States. Fujisawa states that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 149 of the FAMCC speak for themselves and are the best evidence of their contents. Fujisawa denies the remaining allegations in Paragraphs 147 through 154 of the FAMCC that pertain to it, and specifically denies the existence of, and its participation in, any “AWP Scheme” as alleged in Paragraph 153 of the FAMCC.

155-157. Paragraphs 155 through 157 of the FAMCC state legal conclusions to which no response is required. To the extent a response is deemed required, Fujisawa admits that the regulations and statutes cited in Paragraphs 155 through 157 of the FAMCC exist, but denies that Plaintiffs have accurately characterized any conclusions that may be drawn from those regulations and statutes. Fujisawa denies the remaining allegations in Paragraphs 155 through 157 of the FAMCC.

158. Fujisawa admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiffs purport to summarize or characterize 42

C.F.R. 405.517, Paragraph 158 states a legal conclusion to which no response is required. To the extent a response is required, Fujisawa denies the allegations in Paragraph 158 of the FAMCC.

159. Fujisawa denies the allegations in the first sentence of Paragraph 159 insofar as it contains material in quotation marks the source of which is not identified. Fujisawa denies the second sentence of Paragraph 159 insofar as 42 C.F.R. § 405.507 contains no reference to a "ceiling" on reimbursement amounts.

160. Fujisawa admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth, in part, at 42 C.F.R. 405.517 To the extent that Plaintiffs purport to summarize or characterize 42 C.F.R. 405.517, Paragraph 160 of the FAMCC states a legal conclusion to which no response is required. To the extent a response is required, Fujisawa denies the allegations in Paragraph 160 of the FAMCC.

161-162. Paragraphs 161-162 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Fujisawa admits that Program Memorandum AB-99-63 does exist, but denies that Plaintiffs have accurately characterized any conclusion that may be drawn from it. Fujisawa denies the remaining allegations in Paragraphs 161-162 of the FAMCC.

163. Paragraph 163 of the FAMCC states legal conclusions to which no response is required. Fujisawa admits that federal law governs the manner in which Medicare Part B reimburses medical providers for certain drugs. Fujisawa is without knowledge or information sufficient to form a belief as to whether the summary of those laws set forth in Paragraph 163 of the FAMCC is accurate in all instances. Accordingly, to the extent a response is required, Fujisawa denies the allegations in Paragraph 163 of the FAMCC.

164. Upon information and belief, Fujisawa admits the allegations in Paragraph 164 of the FAMCC.

165. To the extent the allegations in Paragraph 165 of the FAMCC refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that there are no government regulations describing how AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs. Fujisawa admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. Fujisawa denies the remaining allegations in Paragraph 165 of the FAMCC that pertain to it.

166-167. Fujisawa states that the April 2003 OIG report referenced in Paragraphs 166 through 167 of the FAMCC speaks for itself and is the best evidence of its contents. Fujisawa denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Fujisawa. Fujisawa denies the remaining allegations in Paragraphs 166 through 167.

168. To the extent the allegations in Paragraph 168 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits certain federal and state agencies have investigated marketing and pricing practices with respect to certain Medicare and Medicaid reimbursable products. Fujisawa denies the remaining allegations in Paragraph 168 of the FAMCC that pertain to it.

169-170. Fujisawa denies the existence of, and its participation in, any “scheme” cited in Paragraph 169 of the FAMCC. Fujisawa states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America referenced in Paragraphs 169 through 170 of the FAMCC speaks for itself and is the best evidence of its contents. Fujisawa denies that Plaintiffs have accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to Fujisawa. Fujisawa denies the remaining allegations in Paragraphs 169 through 170.

171-172. To the extent the allegations in Paragraphs 171 through 172 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 171 through 172 of the FAMCC that pertain to it. Fujisawa further denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 172 of the FAMCC.

173. To the extent the allegations in Paragraph 173 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that it reported AWPs for its medicines to pharmaceutical industry pricing publications before August 2001, but Fujisawa denies that it has done so since. Fujisawa admits the remaining allegations in Paragraph 173 of the FAMCC that pertain to it.

174-190. To the extent the allegations in Paragraphs 174 through 190 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than

Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 174 through 190 of the FAMCC that pertain to it. Fujisawa denies the existence of, and its participation in, any “scheme” as alleged in Paragraphs 174 and 176 of the FAMCC.

191. To the extent the allegations in Paragraph 191 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that the March 30, 2003 Wall Street Journal article referenced in Paragraph 191 of the FAMCC speaks for itself and is the best evidence of its contents. Fujisawa denies that Plaintiffs have accurately characterized the statements or assertions in the March 30, 2003 Wall Street Journal article, or that such are applicable to Fujisawa.

192-196. To the extent the allegations in Paragraphs 192 through 197 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 192 through 196 of the FAMCC that pertain to it.

197. The first two sentences of Paragraph 197 of the FAMCC state legal conclusions to which no response is required. To the extent a response is deemed required, Fujisawa admits that federal statutes and regulations set forth the payment methodology for drugs under Medicare Part B. Fujisawa denies the remaining allegations in Paragraph 197 of the FAMCC.

198. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 198 of the FAMCC and, therefore, denies those allegations.

199-204. To the extent the allegations in Paragraphs 199 through 204 of the FAMCC and its subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that the *Red Book* and the unidentified DOJ report cited in Paragraph 200 of the FAMCC and the pleadings referenced in Paragraphs 202 through 203 of the FAMCC and subparts speak for themselves and are the best evidence of their contents. To the extent the allegations in Paragraphs 199 through 204 of the FAMCC are deemed to include allegations against Fujisawa, they are denied.

205. To the extent the allegations in Paragraph 205 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states the 2003 CMS document cited in Paragraph 205 of the FAMCC is the best evidence of its contents. Fujisawa denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. Fujisawa admits that it sells its medicines in a competitive market and, as such, takes steps to keep certain information relating to its medicines confidential. Fujisawa denies the remaining allegations in Paragraph 205 of the FAMCC that pertain to it.

206-209. To the extent the allegations in Paragraphs 206 through 209 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those

allegations and, therefore, denies those allegations. Fujisawa denies the allegations in Paragraphs 206+ through 209 of the FAMCC that pertain to it.

210. In response to the allegations in Paragraph 210 of the FAMCC, Fujisawa denies that Plaintiffs lacked inquiry or other notice of the issues associated with reliance on AWPs as a pricing benchmark. Fujisawa specifically avers, to the contrary, that such issues were well known for more than a decade before Plaintiffs elected to bring this suit. Fujisawa denies the remaining allegations in Paragraph 210.

211-212. The allegations in Paragraphs 211 through 212 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 211 through 212 of the FAMCC that refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, and, therefore, Fujisawa denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 211 through 212 of the FAMCC that pertain to it.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. To the extent the allegations in Paragraph 213 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 213 of the FAMCC that pertain to it.

214-351. The allegations in Paragraphs 201 through 363 of the FAMCC are directed to other defendants and require no response from Fujisawa. To the extent allegations in Paragraphs 214 through 351 of the FAMCC are deemed to include allegations against Fujisawa, they are denied.

352. The heading contained in the FAMCC immediately prior to Paragraph 352 references the entities Fujisawa Healthcare, Fujisawa USA, and “Fujisawa Pharmaceutical.” Fujisawa states that the FAMCC does not name as a Defendant in this action any entity named Fujisawa Pharmaceutical, and Fujisawa is unaware that the Plaintiffs have served any such entity with the FAMCC. Fujisawa’s Answer to the FAMCC on behalf of Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. does not waive any rights that any entity named “Fujisawa Pharmaceutical” may have. In Answer to Paragraph 352, Fujisawa denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 352 of the FAMCC. To the extent the allegations in Paragraph 352 of the FAMCC are directed to another defendant, Fujisawa is without sufficient knowledge and information to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the existence of, and its participation in, any “Fujisawa Group” as alleged in Paragraph 352 of the FAMCC. Fujisawa admits that Plaintiffs purport to bring this action as alleged in Paragraph 352 of the FAMCC, but Fujisawa denies that Plaintiffs are entitled to a judgment or any relief. Fujisawa denies the remaining allegations in Paragraph 352 of the FAMCC that pertain to it.

353. Fujisawa denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 353 of the FAMCC. Fujisawa admits that there have been reports that the governmental agencies listed in Paragraph 353 of the FAMCC have conducted investigations concerning pricing in the pharmaceutical industry. Fujisawa further admits that it, among others, has participated in a small number of such investigations. Fujisawa denies the remaining allegations of Paragraph 353.

354. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 354 of the FAMCC.

355. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 355 of the FAMCC.

356. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 356 of the FAMCC.

357. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 357 of the FAMCC.

358. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 358 of the FAMCC.

359. To the extent the allegations of Paragraph 359 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without sufficient knowledge and information to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that the report published by the DHHS (AB-00-86) cited in Paragraph 359 of FAMCC referenced in Paragraph 359 of the FAMCC speaks for itself and is the best evidence of their contents, and Fujisawa denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion contained in this document. Fujisawa denies the remaining allegations in Paragraph 359 of the FAMCC.

360. Fujisawa states that the referenced documents speak for themselves in terms of their contents. To the extent the allegations of Paragraph 360 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without sufficient knowledge and information to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that it may sell its medicines at prices below AWP. Fujisawa denies the remaining allegations in Paragraph 360 of the FAMCC.

361. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 361 of the FAMCC.

362. Fujisawa states that the referenced document speaks for itself in terms of its contents. Fujisawa denies the remaining allegations in Paragraph 362 of the FAMCC.

363. Fujisawa denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 363 of the FAMCC. Fujisawa denies the remaining allegations in Paragraph 363 of the FAMCC.

364-501. The allegations in Paragraphs 364 through 501 of the FAMCC are directed to other defendants and require no response from Fujisawa. To the extent allegations in Paragraphs 364 through 501 of the FAMCC are deemed to include allegations against Fujisawa, they are denied.

VI. PLAINTIFFS' CLAIM FOR DAMAGES

502. Fujisawa denies that Plaintiffs have suffered damages or injuries as alleged in Paragraph 502 of the FAMCC. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 502 of the FAMCC and, therefore, denies those allegations.

VII. CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME

503-506. Fujisawa admits that Plaintiffs purport to bring this action as alleged in Paragraphs 503 through 506 of the FAMCC, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged, or that Plaintiffs have pled a proper class or named proper class representatives.

507-512. The allegations in Paragraphs 507 through 512 of the FAMCC state legal conclusions to which no answer is required. Fujisawa denies, however, that Plaintiffs have pled a proper class or named proper class representatives. Further answering, Fujisawa denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 508 and 512 of the FAMCC.

COUNT I¹ **ALLEGED VIOLATIONS OF 18 U.S.C. § 1962(C)**

513-541. The Court dismissed Count I in its Order dated February 25, 2004. Accordingly, Fujisawa does not respond to Paragraphs 513 through 542 of the FAMCC. To the extent a response is required, Fujisawa denies all allegations contained within Count I of the FAMCC.

COUNT II **ALLEGED VIOLATIONS OF 18 U.S.C. § 1962(C)**

542. Answering Paragraph 542 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 541 of the FAMCC.

543. To the extent the allegations in Paragraph 543 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is

¹ Footnote 10 the Plaintiffs' FAMCC incorporates by reference material previously stricken by the Court. Fujisawa denies all allegations incorporated by reference to the extent they pertain to Fujisawa.

without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that Plaintiffs purport to bring this action and to seek relief under Count II of the FAMCC as alleged in Paragraph 543, but Fujisawa denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Fujisawa under Count II. Fujisawa denies the remaining allegations in Paragraph 543 of the FAMCC.

544. The allegations in Paragraph 544 of the FAMCC state a legal conclusion to which no answer is required. Fujisawa denies, however, that Plaintiffs have pled a proper class.

545. To the extent the allegations in Paragraph 545 of the FAMCC and subparts state legal conclusions, Fujisawa avers that no answer is required. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 545 and subparts and, therefore, denies those allegations.

546-550. Fujisawa denies the existence of, or its participation in, any “enterprise,” “AWP Scheme,” or “hidden-profit scheme” as alleged in Paragraphs 546 through 550 of the FAMCC. To the extent the allegations in Paragraphs 546 through 550 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that the unidentified “industry report” cited in Paragraph 550 of the FAMCC speaks for itself and is the best evidence of its contents. Fujisawa denies that Plaintiffs have accurately characterized any alleged “industry report” finding, opinion, statement or conclusion. Fujisawa denies the remaining allegations in Paragraphs 546 through 550 that pertain to it.

551-573. Fujisawa denies the existence of, or its participation in, any “enterprise,” “AWP spread scheme,” “AWP Scheme,” “The Fujisawa Group Manufacturer-PBM Enterprise” and/or “Manufacturer-PBM Enterprise” as alleged in Paragraphs 551 through 573 of the FAMCC. To the extent the allegations in Paragraphs 551 through 573 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations in Paragraphs 551 through 573 of the FAMCC include allegations against Fujisawa, they are denied.

574. The allegations in Paragraph 574 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Fujisawa denies the allegations in Paragraph 574 of the FAMCC.

COUNT III
DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002

575. Answering Paragraph 575 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 574 of the FAMCC. Fujisawa admits that Plaintiffs purport to bring this action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure, but denies that Plaintiffs may properly bring this lawsuit as a class action as alleged in Paragraph 575. Fujisawa further denies any remaining allegations in Paragraph 575.

576. The allegations in Paragraph 576 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Fujisawa denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. To the extent the allegations in Paragraph 576 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies

those allegations. Fujisawa denies the allegations in Paragraph 576 of the FAMCC that pertain to it.

577. Answering the first sentence of Paragraph 577 of the FAMCC, Fujisawa refers to and incorporates its response to Paragraph 576 of the FAMCC. To the extent the allegations in Paragraph 577 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 577 of the FAMCC that pertain to it.

578. The allegations of Paragraph 578 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Fujisawa denies the allegations of Paragraph 578 of the FAMCC. To the extent the allegations in Paragraph 578 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

COUNT IV
ALLEGED VIOLATIONS OF CONSUMER PROTECTION STATUTES

579. Answering Paragraph 579 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 578 of the FAMCC.

580. Fujisawa admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the FAMCC as alleged in Paragraph 580, but Fujisawa denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Fujisawa under Count IV. Fujisawa denies the remaining allegations in Paragraph 580 of the FAMCC.

580. Fujisawa admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the FAMCC as alleged in Paragraph 580. Fujisawa denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Fujisawa under Count IV.

581. To the extent the allegations in Paragraph 581 of the FAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that its principal place of business is located in Deerfield, Illinois. Fujisawa admits that certain states have enacted consumer protection laws, but Fujisawa denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Fujisawa denies the remaining allegations in Paragraph 581 of the FAMCC and subparts that pertain to it.

582-586. To the extent the allegations in Paragraphs 582 through 586 of the FAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 582 through 586 of the FAMCC and subparts that pertain to it. Fujisawa further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 584 and 586 of the FAMCC.

COUNT V
ALLEGED VIOLATIONS OF CONSUMER PROTECTION LAWS –
MEDICARE PART B CO-PAY SUB-CLASS

587. Answering Paragraph 587 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 586 of the FAMCC. Fujisawa admits

that Plaintiffs purport to bring this action as alleged in Paragraph 587 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.

588. Fujisawa admits that the Plaintiffs purport to bring this action as alleged in Paragraph 588 of the FAMCC, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged out to any relief against Fujisawa in Count V. Fujisawa further denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 588 of the FAMCC.

589. Fujisawa admits that Plaintiffs propose the identified individuals as class representatives, but to the extent that the allegations in Paragraph 589 of the FAMCC are directed to Track 1 defendants, they require no response from Fujisawa. Moreover, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 589 of the FAMCC and, therefore, denies those allegations. Fujisawa further denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 589 of the FAMCC.

590. Fujisawa admits that Plaintiffs propose the identified individuals as class representatives, but Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 590 of the FAMCC and, therefore, denies those allegations. Fujisawa further denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 590 of the FAMCC.

591. Fujisawa admits that Plaintiffs seek class certification for these claims, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Fujisawa in Count V.

592-593. The extent that Paragraphs 592 though 593 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 592 through 593 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.. Fujisawa further denies the remaining allegations in Paragraphs 592 through 593 of the FAMCC and subsections.

594. To the extent that the allegations relate to the notice provided to entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 594 and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 594 of the FAMCC.

595. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 595 and, therefore, denies those allegations.

COUNT VI
VIOLATIONS OF CONSUMER PROTECTION LAWS –
THIRD-PARTY PAYORS PART B MEDIGAP CLASS

596. Answering Paragraph 596 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 595 of the FAMCC. Fujisawa admits that Plaintiffs purport to bring this action as alleged in Paragraph 596 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.

597-598. Fujisawa admits that Plaintiffs propose the identified individuals as class representatives, but to the extent that the allegations in Paragraph 589 of the FAMCC are directed to Track 1 defendants, they require no response from Fujisawa. Fujisawa admits that the Plaintiffs purport to bring this action as alleged in Paragraph 597 through 598 of the FAMCC, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner

alleged out to any relief against Fujisawa in Count V. Fujisawa further denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 597 through 598 of the FAMCC.

599. Fujisawa admits that Plaintiffs seek class certification for this claim, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Fujisawa in Count VI.

600-601. The extent that Paragraphs 600 though 601 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 600 through 601 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa further denies the remaining allegations in Paragraphs 600 through 601 of the FAMCC and subsections.

602. To the extent that the allegations relate to the notice provided to entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 602 and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 602 of the FAMCC.

603. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 595 and, therefore, denies those allegations.

COUNT VII
VIOLATIONS OF CONSUMER PROTECTION LAWS –
PHYSICIAN-ADMINISTERED CLASS FOR CONSUMERS AND TPPS

604. Answering Paragraph 587 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 603 of the FAMCC. Fujisawa admits

that Plaintiffs purport to bring this action as alleged in Paragraph 604 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.

605. Fujisawa admits that Plaintiffs seek class certification for this claim, but Fujisawa denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Fujisawa in Count VII.

606. Fujisawa admits that Plaintiffs propose the identified individuals as class representatives in this paragraph, but to the extent that the allegations in Paragraph 589 of the FAMCC are directed to Track 1 defendants, they require no response from Fujisawa. Moreover, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 606 of the FAMCC and, therefore, denies those allegations. Fujisawa further denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 606 of the FAMCC.

607-608. Fujisawa denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraphs 607 through 608 of the FAMCC.

609. Fujisawa denies this allegation insofar as it is inconsistent with this Court's rulings.

610. Fujisawa denies that Plaintiffs have pleaded a proper class or named proper class representatives. Fujisawa denies the remaining allegations in Paragraph 610 of the FAMCC.

611-613. The extent that Paragraphs 611 though 613 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 611 through 613 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as

to the truth of those allegations and, therefore, denies those allegations. Fujisawa further denies the remaining allegations in Paragraphs 611 through 613 of the FAMCC and subsections.

COUNT IX
CIVIL CONSPIRACY

(AGAINST ALL DEFENDANTS IDENTIFIED, FOR CONSPIRING WITH PBMS)

614. Answering Paragraph 614 of the FAMCC, Fujisawa re-alleges and incorporates its responses to the allegations in Paragraphs 1 through 613 of the FAMCC.

615. Fujisawa admits that Plaintiff CMHV purports to bring this action as alleged in Paragraph 615 of the FAMCC, but Fujisawa denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 615 of the FAMCC and, therefore, denies those allegations.

616-619. To the extent the allegations in Paragraphs 616 through 619 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 616 through 619 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 616 through 619 of the FAMCC and subparts.

620-621. The allegations in Paragraphs 620 through 621 of the FAMCC state legal conclusions to which no response is required. To the extent a response is deemed required, Fujisawa denies the allegations in Paragraphs 620 through 621 of the FAMCC.

VIII. PRAYER FOR RELIEF

UNNUMBERED “WHEREFORE” PARAGRAPHS AND REQUEST FOR JURY TRIAL

Fujisawa denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and “WHEREFORE” paragraph following Paragraph 621 of the FAMCC.

Listed below, Fujisawa has provided a list of defenses without assuming any burden of proof:

First Defense

Plaintiffs and the putative class fail to state a claim against Fujisawa upon which relief may be granted.

Second Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the filed rate doctrine.

Fourth Defense

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Fujisawa as alleged in the FAMCC.

Fifth Defense

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is

barred from seeking recovery against Fujisawa based on the FAMCC pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Sixth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the various States whose laws are or become relevant in the course of this multidistrict litigation.

Seventh Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Fujisawa in judicial, legislative or administrative proceedings of any kind or at any level of government.

Eighth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

Ninth Defense

Any and all actions taken by Fujisawa with respect to any of the matters alleged in the FAMCC were taken in good faith and in accordance with established industry practice.

Tenth Defense

Plaintiffs' and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and

Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

Twelfth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred because Fujisawa has complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

Fourteenth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate Fujisawa's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, and the analogous provisions of the constitutions of the States whose laws are or become relevant during the course of this multidistrict litigation, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

Fifteenth Defense

Fujisawa's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

Sixteenth Defense

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations, and fail to plead with particularity the fraudulent concealment and multi-source medicine allegations against Fujisawa contained in the FAMCC.

Seventeenth Defense

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against Fujisawa as required by Fed. R. Civ. P. 9(b).

Eighteenth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred, in whole or in part, because Fujisawa did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against Fujisawa that Plaintiffs and the putative class allege to be false or misleading, Fujisawa had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Nineteenth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred because Fujisawa did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

Twentieth Defense

Plaintiffs' and the putative class' RICO claims against Fujisawa are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

Twenty-First Defense

Plaintiffs' and the putative class' RICO claims against Fujisawa are barred, in whole or in part, due to their failure to plead facts showing that Fujisawa and the PBMs are ongoing organizations whose members function as continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

Twenty-Second Defense

Plaintiffs' and the putative class' RICO claims against Fujisawa are barred, in whole or in part, due to their failure to allege that Fujisawa conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

Twenty-Third Defense

Plaintiffs and the putative class lack standing to bring their RICO claims against Fujisawa because they cannot show Fujisawa directly caused their alleged injuries as required by 18 U.S.C. § 1964(c); *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *Platten v. HG Berm. Exempted Ltd.*, 437 F.3d 118, 132 (1st Cir. 2006); and *George Lussier Enters. v. Subaru of New Eng., Inc.*, 393 F.3d 36, 51 (1st Cir. 2004) .

Twenty-Fourth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Fujisawa are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

Twenty-Fifth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Fujisawa are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.

Twenty-Sixth Defense

Fujisawa denies that Plaintiffs and the putative class have valid consumer protection claims against Fujisawa under any of the State consumer protection laws alleged in this Complaint or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Fujisawa pleads all available defenses under the Acts.

Twenty-Seventh Defense

Any allegedly fraudulent statements or conduct of Fujisawa did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Twenty-Eighth Defense

Fujisawa' conduct was not "knowing," "deceptive," "misleading," "unlawful," a "misrepresentation" or "illegal" as required under certain state consumer protection laws, including without limitation t any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Twenty-Ninth Defense

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against Fujisawa, they are not entitled to such relief because they have an adequate remedy at law.

Thirtieth Defense

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against Fujisawa under certain state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Thirty-First Defense

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of Fujisawa as required under certain state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Thirty-Second Defense

Any allegedly fraudulent statement or conduct of Fujisawa was not consumer-oriented as required under certain consumer protection law, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

Thirty-Third Defense

To the extent the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation do

not recognize a private right of action, Plaintiffs are not entitled to relief under the applicable statutes.

Thirty-Fourth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation bar class actions, Plaintiffs are not entitled to relief under the applicable statutes.

Thirty-Fifth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit claims to those brought by “consumers,” Plaintiffs are not entitled to relief under the applicable statutes.

Thirty-Sixth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to send a written demand for relief to Defendants prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Thirty-Seventh Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to attempt Alternative Dispute Resolution prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Thirty-Eighth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs provide notice of the practice at issue to the relevant State Attorney General, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

Thirty-Ninth Defense

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit Plaintiffs' available remedies, Plaintiffs are not entitled to their requested relief under the applicable statutes.

Fortieth Defense

Plaintiffs' and the putative class' claims against Fujisawa for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Forty-First Defense

Plaintiffs' and the putative class' claims for injunctive relief against Fujisawa are barred by the doctrines of *in pari delicto* and/or unclean hands.

Forty-Second Defense

This action cannot be maintained as a class action because (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the

procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate Fujisawa' rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of any State whose consumer protection laws are specified in this Complaint and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to Fujisawa' right to procedural and substantive safeguards, which include traditional defenses to liability.

Forty-Third Defense

Plaintiffs' and the putative class' claims against Fujisawa under the various state consumer protection and consumer fraud statutes are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

Forty-Fourth Defense

Plaintiffs' and the putative class' claims against Fujisawa under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes are barred to the extent (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2) those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

Forty-Fifth Defense

Third party payor Plaintiffs' and third party payor putative class members' claims against Fujisawa are barred, in whole or part, with respect to any alleged overcharge or supra-

competitive price on the ground that third party payors passed on any effect of the alleged supra-competitive prices to their customers or employees in the form of higher premiums, co-pays or other charges.

Forty-Sixth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred, in whole or in part, with respect to any alleged overcharge or supra-competitive price because such supra-competitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

Forty-Seventh Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred, in whole or in part, due to their failure to join indispensable parties.

Forty-Eighth Defense

Plaintiffs' and the putative class' claims against Fujisawa are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the FAMCC.

Forty-Ninth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superseding conduct of third parties.

Fiftieth Defense

Plaintiffs' and the putative class' claims against Fujisawa for damages are barred, in whole or in part, (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any

fault, if any exists, attributable to Fujisawa; (2) because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the FAMCC; (3) by the doctrine of consent and/or ratification to the extent that Plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by Fujisawa after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

Fifty-First Defense

Fujisawa is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

Fifty-Second Defense

Any damages recovered by the Plaintiffs and the putative class from Fujisawa must be limited by the applicable statutory ceilings on recoverable damages.

Fifty-Third Defense

Plaintiffs and the putative class fail to allege facts or a cause of action against Fujisawa sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

Fifty-Fourth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against Fujisawa: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the FAMCC are legally insufficient to support a claim for punitive damages against Fujisawa; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Fujisawa prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may

be imposed and are void for vagueness in violation of Fujisawa' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitutions and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Fujisawa' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, of subsequent judgments against Fujisawa for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Fujisawa' medicines would constitute impermissible multiple punishments for the same wrong, in violation of Fujisawa' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Fujisawa' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Fujisawa the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective

assistance of counsel, would violate Fujisawa' rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Fifth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against Fujisawa cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Fujisawa, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is not properly instructed regarding Plaintiff's and the putative class' burden of proof with respect to each and every element of a claim for punitive damages, or (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Fujisawa' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Sixth Defense

To the extent punitive damages are sought, Plaintiff's and the putative class' claim for punitive damages against Fujisawa cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Fujisawa' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Fujisawa' right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Seventh Defense

Plaintiffs' and the putative class members' claims are barred, in whole or in part, because they conflict with federal statutes and regulations that comprise a comprehensive regulatory regime governing the amounts paid to providers for Medicare Part B-covered drugs.

Fifty-Eighth Defense

Plaintiffs' and the putative class members' claims against Fujisawa under the various state unfair and deceptive trade practice or consumer protection or consumer fraud statutes are barred in whole or in part because Fujisawa's conduct was not knowing, unfair, deceptive, misleading, unlawful, a misrepresentation or illegal.

Fifty-Ninth Defense

Plaintiffs and the putative class members are not entitled to the relief requested in the Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

Sixtieth Defense

Plaintiffs and the putative class members are barred from recovery because the representations and actions alleged by Plaintiffs were not and are not material, in that they were not and are not likely to affect the decisions or conduct of Plaintiffs and putative class members, or to have caused consumers or Third Party Payors to have chosen differently, but for such alleged representations or actions, in light of the information available and known to consumers and Third Party Payors, and in that the alleged representations and actions were not likely to mislead consumers or Third Party Payors acting reasonably under the circumstances.

Sixty-First Defense

Plaintiffs' and the putative class members' claims against Fujisawa under the various state and unfair deceptive trade practice or consumer protection or consumer fraud statutes are barred in whole or in part because excess-provider-profit claims are inherently speculative and subjective and not subject to judicial resolution.

Sixty-Second Defense

Plaintiffs' and the putative class members' claims fail, in whole or in part, because of improper claim splitting.

Sixty-Third Defense

Plaintiffs' and the putative class members' antitrust claims against Fujisawa are barred in whole or in part because: (1) they have not suffered any antitrust injury; (2) they lack standing; and/or (3) the alleged conspiracy does not make economic sense and is economically implausible.

Sixty-Fourth Defense

Any alleged restraints complained of in the FAMCC are ancillary to legitimate, pro-competitive activity.

Sixty-Fifth Defense

Plaintiffs and the putative class members are precluded from recovery because the representations and actions alleged by Plaintiffs were not intended to deceive Plaintiffs or the putative class members.

Sixty-Sixth Defense

Fujisawa is not liable to Plaintiffs or to the putative class members because it had no duty to disclose the information allegedly not disclosed.

Sixty-Seventh Defense

Plaintiffs' and the putative class members' claims against Fujisawa under Section 1 of the Sherman Act, 15 U.S.C. § 1, are barred to the extent recovery is based on indirect purchases of medicines.

Sixty-Eighth Defense

Plaintiffs' and the putative class members' antitrust claims against Fujisawa under various state and unfair trade and competition statutes are barred in whole or in part to the extent those statutes: (1) do not allow (or did not allow at the time of the alleged conduct) recovery of damages by indirect purchasers; and/or (2) govern conduct that is predominantly intrastate in nature.

Sixty-Ninth Defense

Plaintiffs' and the putative class members' claims against Fujisawa are barred, in whole or in part, by the doctrines of assumption of risk and/or comparative fault or negligence.

Seventieth Defense

Plaintiffs and the putative class members may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

Seventy-First Defense

Plaintiffs and the putative class members fail to allege facts or a cause of action against Fujisawa sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

Seventy-Second Defense

Fujisawa adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Seventy-Third Defense

Fujisawa hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Fujisawa also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than any State whose consumer protection laws are specified in this Complaint and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, Fujisawa prays that this Court:

1. Dismiss the Fourth Amended Master Consolidated Class Action Complaint with prejudice and enter judgment in favor of Fujisawa and against Plaintiffs;
2. Award Fujisawa its costs and expenses; and
3. Grant such other and further relief for Fujisawa as this Court deems just and proper.

Respectfully Submitted,

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Attorneys for Defendants Fujisawa
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Inc.

Dated: May 15, 2006

CERTIFICATE OF SERVICE

I certify that a true and correct copy of Fujisawa Healthcare, Inc.'s and Fujisawa USA, Inc.'s Answer To Plaintiffs' Fourth Amended Master Consolidated Class Action Complaint was delivered to all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending, on May 15, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Andrew L. Hurst

Andrew L. Hurst